UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,262	04/07/2004	Jiashi Zhu	21798.NP	8617

20551 7590 02/13/2006

THORPE NORTH & WESTERN, LLP.
8180 SOUTH 700 EAST, SUITE 200
SANDY, UT 84070

EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,262	ZHU ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *13-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/13/04;3/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-12, in the reply filed on November 30, 2005 is acknowledged.

Claims 1-12 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to Claim 1, although the use of common names or traditional/ethnopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical matter noted in this application. Applicant may overcome the rejection by inserting (*Hippophae rhamnoides*) after "sea buckthorn" in line 4 of Claim 1.

Claim 1 is rendered vague and indefinite by the term "extract" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art).

For example, is the extract obtained via extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? In addition, from what part(s) of the plant is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the desired functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the step(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

Claim 10 recites "the oral administration" in line 1. There is a lack of clear antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (A8).

Applicant claims a method of controlling serum lipid concentrations in a subject comprising: (a) providing a composition containing a therapeutically effective amount of a sea buckthorn extract and an inert carrier, and (b) administering the composition to a subject. Applicant further claims a method as in claim 1, wherein the controlling is reducing serum lipid concentrations in a subject. Applicant further claims a method as in claim 2, wherein the serum lipid is a triglyceride; wherein the serum lipid is total cholesterol; and, wherein the serum is a low-density lipoprotein. Applicant further claims the method as in claim 1, wherein the controlling is preventing a concentration increase in serum lipid selected from the group consisting of triglycerides, cholesterol, low density lipoprotein, and combinations thereof; wherein the controlling is elevating high density lipoprotein serum concentrations; wherein the inert carrier is selected from a Markush group recited in claim 8; wherein the sea buckthorn extract is administered orally. Applicant further claims a method as in claim 9, wherein the oral administration is performed using a dosage selected from the group consisting of beverages,

effervescent beverages, liquids, syrups, elixirs, suspensions, tablets, powders, capsules, gel capsules, confections, candies, bars, lozenges, and combinations thereof. Applicant further claims a method as in claim 1, wherein the composition further comprises and active ingredient selected from the group consisting of herbal extracts, botanical extracts, vitamins, minerals, amino acids, proteins, enzymes, and combinations thereof.

Li teaches a method for controlling serum lipid concentration in a subject comprising orally administering a therapeutically effective amount of dietary fibers extracted from sea buckthorn rind and oat bran. The administration of the dietary fiber complex decreased the serum levels of triglyceride, and low density lipoprotein, and increased high density lipoprotein serum concentrations in the subjects.

The reference anticipates the claimed subject matter.

Claims 1, 2, 4, 6, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chou et al. (A5).

Applicant's claimed invention was set forth above.

Chou teaches a method of lowering the serum cholesterol and increasing the amount of high-density lipoprotein-associated cholesterol in a subject comprising orally administering a therapeutically effective amount of oil extracted from the seeds of sea buckthorn to a subject.

The reference anticipates the claimed subject matter.

Claims 1, 2 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (A2).

Applicant's claimed invention was set forth above.

Wang teaches a method for controlling serum lipid concentrations in a subject comprising administering a therapeutically effective amount of a tea beverage sea buckthorn extract, honey, malodextrin and green tea powder, and additional plant extracts to a subject.

The reference anticipates the claimed subject matter.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (A11).

Applicant's claimed invention was set forth above.

Yang teaches a method for controlling serum lipid concentrations in a subject comprising the oral administration of an effective amount of a sea buckthorn oil extract (sea buckthorn pulp oil) in the form of a capsule (with added alpha-tocopherol) to a subject, wherein the method increased high density lipoprotein serum concentrations. In another instance, Yang teaches that the oral administration of a sea buckthorn oil extract (sea buckthorn seed oil) in the form of a capsule (with added alpha-tocopherol) to a subject reduced the serum concentrations of triglycerides and low-density lipoproteins. *See* Table 5 on page 628.

The reference anticipates the claimed subject matter.

Claims 1, 2, 4-6 and 9 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhang et al. (A9).

Applicant's claimed invention of Claims 1-6 and 9 was set forth above.

Zhang teaches a method for controlling serum lipid concentration in a subject comprising either orally administering or injecting a therapeutically effective amount of a sea buckthorn extract by reducing both total cholesterol and low density lipoprotein

The reference anticipates the claimed subject matter.

Claims 1 and 7-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Eccleston et al. (A6).

Applicant's claimed invention of Claims 1 and 7-11 was set forth above.

Eccleston teaches a method of controlling serum lipid concentration in a subject comprising orally administering a therapeutically effective amount of a juice extract of sea buckthorn (SBJ) and additional daily intake of vitamin C, alpha-tocopherol, beta-carotene and flavonoids through sea buckthorn supplementation. A 20% and 17% increase in serum high density lipoprotein and triglycerols was observed, as well as a moderate decrease in the susceptibility of low density lipoprotein to oxidation was effected by SBJ supplementation.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (A8) in view of Fritz (A*), Dente (B*), Singh et al. (U), Hagiwara (C*), Cai et al. (V), Wang (N), Kominato (A1, JP 04338336 A), Sodimu et al. (W), Ueda et al. (D*) and Sawada et al. (O, translation of foreign language patent provided herein.), and further in view of Marin (E and/or F).

Applicant's claimed invention of Claims 1-11 was set forth above. Applicant further claims a method as in claim 1, wherein the composition further comprises a cortisol controlling agent selected from the group consisting of ashwagandha, beta-sitosterol, Epimedium, garlic, L-theanine, magnolia bark extract, phosphatidylserine, and combinations thereof.

The teachings of Li are set forth above. Li teaches the instantly claimed method except for wherein the composition further comprises the instantly claimed ingredients. However, it would have been obvious to one of ordinary skill in the art to add a cortisol controlling agent to the method of controlling serum lipid concentrations in a subject taught by Li to provide the instantly claimed invention because at the time the invention was made it was well-known in the art of herbal medicine the health promoting effects of each of ashwagandha, beta-sitosterol, Epimedium, garlic, L-theanine, magnolia bark

extract and phosphatidylserine. For instance, with regard to phosphatidylserine, Fritz teaches a nutritional supplement soy derived phosphatidylserine that suppresses the release of cortisol in a subject under conditions wherein release would be otherwise increased, such as physical stress or mental stress or dieting or a substantial increase in food intake, which result in the triggering of elevated adrenal glucocorticoids that adversely affects the body in elevated levels. Fritz further teaches a method of orally administering phosphatidylserine to a subject experiencing physiological or mental stress to inhibit muscle loss, to promote muscle gain for health and fitness, and to inhibit protein catabolism by suppressing production of elevated and toxic levels of the stress hormone cortisol. Like Fritz, Dente teaches a dietary supplement comprising at least one adrenal support substance, such as ashwagandha, which is orally administered to a subject to support, maintain and/or improve adrenal functions and to reduce stress. In another instance, Singh teaches that that the administration of an extract of *Withania somnifera* (ashwagandha) to animals subjected to physical stress prevented increase in adrenal weight and cortisol content of adrenals during stress. Thirdly, Hagiwara teaches a composition comprising beta-sitosterol, which can be incorporated into various food products or drinks. Hagiwara also teaches that the beta-sitosterol composition has anticholesterol action and antioxidant action, in Column 4, lines 59-65. Fourthly, Cai teaches that the administration of Epimedium to patients decreased the level of adrenocorticotrophin in the treated patients. In another instance, Wang teaches a powdered composition comprising Epimedium that is useful for lowering lipid levels and reducing obesity. Fifthly, Kominato teaches an anti-obesity agent comprising garlic

formulated into tablets, granules or powders that has lipid metabolic activity, resulting in lower levels of free fatty acid and triglyceride. In another instance, Sodimu teaches that the administration of effective amounts of garlic oil to a rats maintained on a high-fat high-cholesterol diet reduced the total lipids, cholesterol and triglycerides in the animals. With regard to theanine, Ueda teaches a composition comprising L-theanine, which is useful in the treatment of various disease conditions, including the amelioration of obesity in patients, in Column 4, lines 12-23. Finally, with regard to magnolia bark extract, Sawada teaches a magnolia bark extract as an inhibitor of cholesterol absorption inhibitor and having activity against cholesterol acyltransferases. Sawada teaches that the oral administration of the plant extract is useful in preventing and treating hyperlipemia or arteriosclerosis caused by the accumulation of cholesterol in humans. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add any of the claim-designated cortisol controlling agents to the method of controlling serum lipid concentrations in a subject taught by Li to provide the claim-designated method of treatment because each of the aforementioned references clearly teach the beneficial functional health promoting effects for the administration of the claim-designated ingredients to a subject in need of controlling serum lipid concentrations by the administration of therapeutically effective amounts of a cortisol controlling agent.

At the time the invention was made, it also would have been obvious to one of ordinary skill in the art, and one of ordinary skill would have been motivated and one would have had a reasonable expectation of success to add a cortisol controlling agent

to the method of controlling serum lipid concentrations in a subject taught by Li to provide the instantly claimed invention because at the time the invention was made Marin (E, US 6,642,236 B1) taught a method for the prophylactic treatment of cardiovascular disease and arteriosclerotic manifestations comprising the administration of an effective amount of a cortisol inhibitor to a patient in need in thereof. In another patent, Marin (F, US 6,274,582 B1) teaches that excessive secretion of cortisol is a largely responsible or the development of 'Metabolic Syndrome', also designated 'Syndrome X', the 'Insulin Resistance Syndrome', *etc.*, which is characterized by the aforementioned clinical manifestations or cardiovascular disease and arteriosclerosis, in Column 1, lines 14-44. Also *see* Column 2, lines 15-25, wherein Marin teaches that cortisol is responsible for the metabolism of proteins, carbohydrates, and lipids in most tissues; and that cortisol inhibitors should be understood as agents reducing but not completely inhibit the synthesis of cortisol. Please note that the teachings of Marin are used herein only to establish the nexus between controlling serum lipid concentrations in a subject by the administration of therapeutically effective amounts of a sea buckthorn extract, such as the method taught by Li which reduced serum triglycerides, total cholesterol, low-density lipoprotein with an increase in elevated high-density lipoprotein, and controlling cortisol synthesis in a subject by the administration of an effective of amount of a cortisol controlling agent to a subject, such as the methods of treatment taught by Fritz, Dente, Singh, Hagiwara, Cai, Wang, Kominato, Sodimu, Ueda and Sawada, to provide a comprehensive method of treating various clinical manifestations as a result of high serum lipid concentrations in a subject and increased

cortisol secretion, *e.g.,* cardiovascular disease and arteriosclerotic manifestations, obesity, hyperlipemia, and cancer. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art to add any of the claim-designated cortisol controlling agents to the method of controlling serum lipid concentrations in a subject taught by Li to provide the instantly claimed method of treatment because at the time the invention was made Marin (E and/or F) taught that the administration of a cortisol controlling agent to a subject is useful in the treatment of disease conditions, such as cardiovascular disease, hyperinsulinemia, abdominal obesity (caused by an accumulation of intra-abdominal fat), elevated serum lipids, and raised blood pressure; and, each of Fritz, Dente, Singh, Hagiwara, Cai, Wang, Kominato, Sodimu, Ueda and Sawada taught that the administration of therapeutically effective amounts of each of phosphatidylserine, ashwagandha, beta-sitosterol, Epimedium, garlic, L-theanine and magnolia bark extract was useful in the control of cortisol synthesis or the treatment of disease conditions known in the art of medicine manifested by excessive secretion of cortisol; and, Li suggests that the administration of therapeutic amounts of a sea buckthorn extract is useful in the prevention and treatment of atherosclerosis and coronary heart disease. Hence, one of ordinary skill in the art would have been highly motivated to add the instantly claimed cortisol controlling agents to the method taught by Li to provide the instantly claimed method of treatment because like Marin, Fritz teaches that an increased level of cortisone can harden arteries, lower immunity, and promote cancer growth, in Column 3, lines 3-14. However, unlike Marin, Fritz teaches the administration of a natural food supplement, such as the referenced soy-derived phosphatidylserine,

having cortisol suppressing activity can serve as an alternative to cortisol suppression using anabolic steroids or other controversial drugs known to have adverse medical side effects; and, therefore, one would have been highly motivated and one would have a reasonable expectation of success to add the claim-designated cortisol controlling agents to the Li' method since each of phosphatidylserine, ashwagandha, beta-sitosterol, Epimedium, garlic, L-theanine and magnolia bark extract are natural plant extracts, such as the composition taught by Fritz having cortisol-inhibiting activity.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients to the method of treatment taught by Li because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
February 4, 2006